

Under 21 CFR 1040.10(f)(3) Class IIb laser systems are required to incorporate remote interlock connector(s).

The LAM is designed not to allow for dismantling or servicing by the user. The unit's front, rear, and top housing parts are permanently bonded together. All servicing is done at Insight Technology, Inc.

Under 21 CFR 1040.10(f)(4) Class IIb laser systems are required to incorporate a key control. The LAM requires both the mode selector switch, to be in operative mode position as well as use of the paddle switch or tethered remote switch to turn the unit on. An additional "key control" would limit the effective use of this product, and compromise the safety of the user.

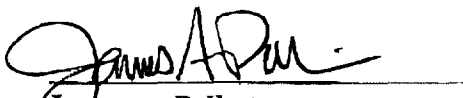
Under 21 CFR 1040.10(f)(5) Class IIb laser systems are required to incorporate an emission indicator.

Given the intended use of the LAM, such an audible or visible indicator or delayed emission of the lasers could seriously compromise the safety of the user.

The restriction of sales of the LAM and intended use of the LAM are consistent with other aiming devices of its' type. Safety and use of the LAM is almost intuitive to the users of this product.

If any further information about the report or the request for variance is needed, please do not hesitate to contact me.

Sincerely,



James A. Pellerin
Program Manager (ext. 1450)